DENTAL HI TEC

SleeperOne®

USER GUIDE

IMPORTANT : TO BE READ BEFORE FIRST USE

www.dentalhitec.com

Version 2.0-Gb

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SleeperOne®

Precise

Light

Effective

Dear User,

Thank you for purchasing SleeperOne.
It's characteristics and functions will meet up to all of your expectations concerning electronically controlled injections.
It is important that you perfectly handle the needle (orientation, angulation, delicacy...) as described in this guide.
Only the handling of these two parameters will guarantee complete success in anaesthesia.

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Security rules

TO BE READ IMPERATIVELY BEFORE FIRST USE

SleeperOne is an electronic dental anaesthesia system designed for local injections before and/or during treatment.

SleeperOne is a modern alternative to traditional dental syringes. The dentist should take the usual precautions to ensure the success of every dental anaesthetic injection.

GENERAL RECOMMENDATIONS

- SleeperOne® must only be used by a qualified dental surgeon.
- During use, the handpiece must be under the dentist's constant surveillance.
- Do not leave SleeperOne® within reach of children.
- Do not expose your device to the sun or leave it near a radiator or an air-conditioner.
- Do not expose SleeperOne® to water or chemical products.
- The plug of the power supply serves as a cut-off and must remain accessible.
- Imperatively wear disposable surgical gloves when using SleeperOne

RECOMMENDATIONS FOR USE

- Only use 1.8ml glass anaesthetic cartridges, with plastic protection film (to easily withdraw the cartridge in case of breakage).
- Refer to the cartridge manufacturers' recommendations to know the quantities that can be injected per session.
- For security reasons, do not screw or unscrew the needle close to your patients and protect them with safety glasses.
- Each SleeperOne needle, cartridge and accessory must be used only on one single patient to prevent risks of contamination.
- Never re-use the needles and anaesthetic cartridges, each of these items must be destroyed after use in an incinerator allocated for this purpose.
- The containers must be disinfected and sterilized after each anaesthesia (see procedure p.12).
- The holder and handpiece (p.5) must be disinfected after each patient (see the indications of disinfectant product manufacturers).
- Do not leave the needles without protection. Systematically replace the protection after use, using the recapping system on the handpiece holder (p.7).

BLOCKED NEEDLE

- Never bend a needle
- In the case of a blocked needle, SleeperOne will shut down. Replace the blocked needle with a new one.

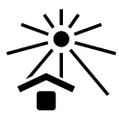
PROTECTION AGAINST ELECTRIC SHOCKS

- The connection must be made on an alternative single-phase circuit.
- **The external voltage should be identical to that on the material safety data sheet located under the control unit.**
- The electrical installation must have a security circuit breaker.
- Before every use, check the condition of the plug and power cable.
- Do not pull on the cable to remove the plug from the power socket.

Security level:

- Handpiece and control box cables: very low security voltage (VLSV-18V).

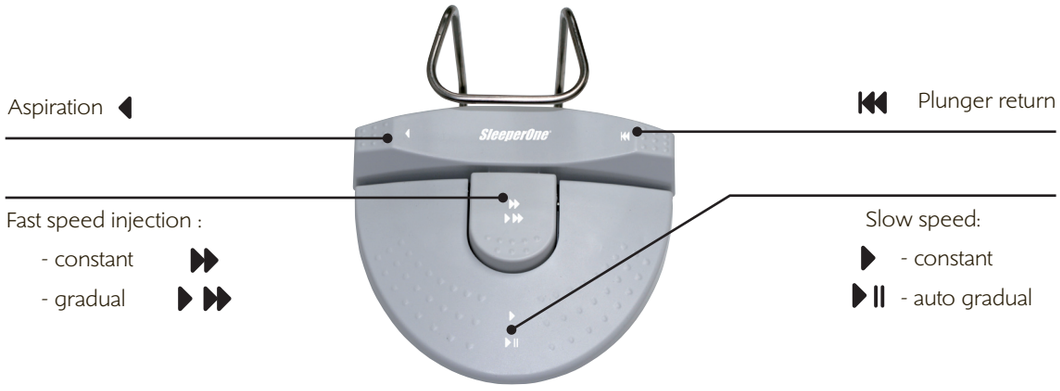
Keep out of direct light and sun



Keep dry

Description of the control pedal

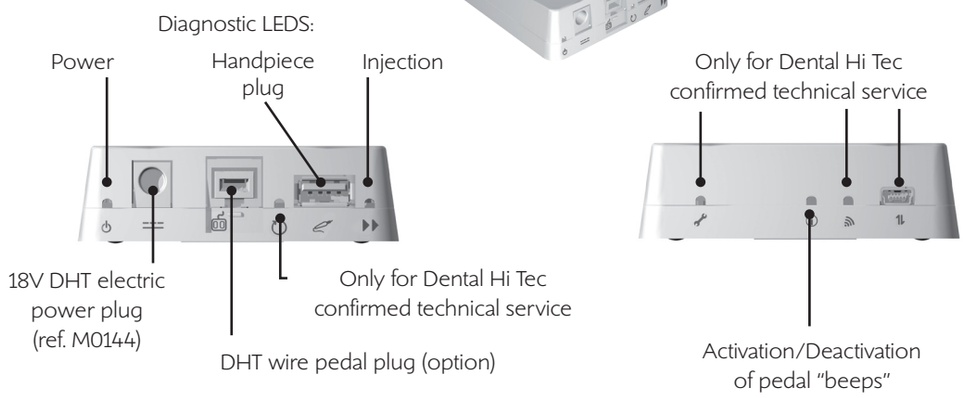
All of the commands have an "all or nothing" function. The SleeperOne wireless pedal does not require an accumulator. It is by pressing on the pedal that you create the energy necessary for the device to function.



Description of the wire control pedal (option)

All of the commands have an «all or nothing» function.

Description of the control box


Diagnostic LEDS:
Power
Handpiece plug
Injection
Only for Dental Hi Tec confirmed technical service
18V DHT electric power plug (ref. M0144)
Only for Dental Hi Tec confirmed technical service
DHT wire pedal plug (option)
Activation/Deactivation of pedal "beeps"

18V DHT electric power plug
(Ref. M0144)

Control box fixing adhesives
(Ref. SA0226)

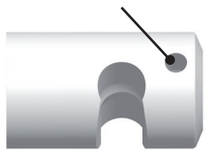
Description of the handpiece and accessories

SleeperOne Handpiece

Injection resistance information window

Plastic container
(Ref. SA050 - FR) .

Integrated needle recapping system



Handpiece support
(Ref. C3140)

Needles DHT

DHT Needles have a patented bevel and a specific base indicator enabling an easy and painfree penetration.

Their specific bevels, contrary to standard needles, present identical cutting proprieties to a scalpel blade. Therefore bringing forward 3 advantages:

- DHT needles incise the tissues instead of tearing them, allowing a painfree penetration of the mucosa.
- For intraligamentaries and intraseptals they also have a higher penetration capacity compared to standard models.
- The force of penetration is reduced by 29% (Study by A. Steele and coll - Submitted).

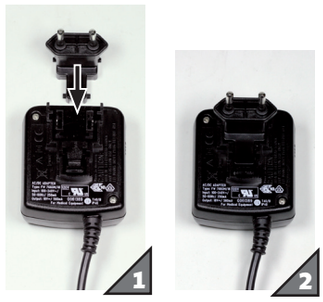
- Respect the model of needle corresponding to the type of anaesthesia performed to obtain maximal results and prevent needle breakages or post operative side effects.
- Consult the instructions in the boxes before use.

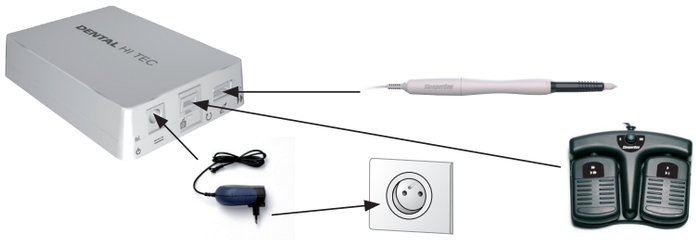
Type of needle : Hub :	30G - 16 mm **White**	30G - 9 mm **Green**	27G - 13 mm **Grey**
Infiltration (free mucosa)	X		
Infiltration attached mucosa	X	X	
Intraseptal adult		X	X
Intraseptal child		X	
PDL-Intraligamentary		X	
Palatal	X	X	

Prepare your SleeperOne

Connection

Assemble the plug adaptor corresponding to your country (photos 1 & 2).
Connect the handpiece, power supply and wire pedal (option) as indicated below then plug in the power supply to your mains installation.
Your SleeperOne is ready to work.





110/220V

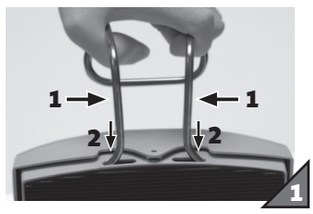
Assembling the wireless foot pedal

Put in place the pedal hoop.

Present the hoop to the back of the pedal, squeeze it to allow the arms to enter the oval slots situated at the back of the pedal. (photo 1).

Push in the hoop and release; the extremities should appear in the 2 windows situated beneath the pedal (photo 2)

Your wireless pedal is ready to work. It does not require an accumulator. It is by pressing on the pedals that you create the energy necessary for it to function.



Never place the pedal under the chair during lowering to prevent squashing the pedal's hoop and damaging the chair.

The wireless pedal is the outcome of advanced research. The wireless liaison is very reliable but like any radio system it can be disturbed by external elements : metal furniture (stainless steel...), immediate proximity of a strong radio transmitter (no mobile phones within 1.5m of the control box), a disturbing electronic device (computer...). We therefore highly recommend that you carefully choose the position of the control box and pedal so they can communicate without being disturbed.

This pedal is wireless. The movement of your foot on the pedal creates the energy necessary for the system to function. It is therefore essential to perform fast and strong presses and releases. A slow or incomplete movement may not create enough energy to transmit the information to the control box.
If a pedal release does not have any effect (the injection remains active), you simply have to press again on the same pedal to immobilize the device. The handpiece remains under the dentist's constant supervision who must remove it from the work area in case of dysfunction.

A technical question? Our team is ready to answer you on +33 241 560 590 or sleeperone@dentalhitec.com

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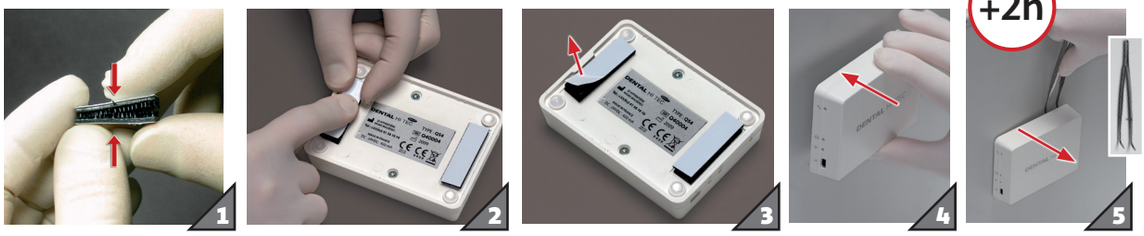
Install the control box

Choosing the site:
The LEDS on the control box work only as a diagnostic in case of malfunction, it can therefore be hidden below your instrument holder or on the side of a piece of furniture,... (see fig. 6)

The control box comes with non-slip feet allowing it to be placed on a horizontal surface. It is also possible to fix it on a vertical surface using the supplied adhesives (see photos below).
It is recommended to wait 2h minimum before unfixing your control box with a forceps to avoid the adhesives from coming loose.
The fixation is optimal after 12h.

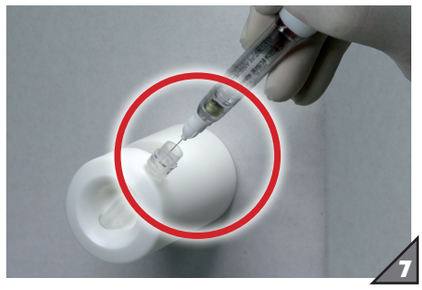
To ensure good communication between the control box and wireless pedal, avoid obstacles, especially metallic (computers, boxes...) between the 2 elements. Do not fix / place the box on an electronic device (computer...). Do not place a mobile phone within 1.5 metres of the box, pedal or power supply.



Install the handpiece support

SleeperOne is going to be the device for all of your anaesthesias. The handpiece must therefore always be immediately on hand just like your turbine or micro motor.

The handpiece support is designed to be placed either on the left or right of a vertical surface, opening at the top.
-Before sticking the handpiece support clean the surface with the «pochette de nettoyage» supplied with the device.
- Remove the adhesive's protective film and position the support on the clean surface.
- Wait 24h before placing the handpiece in the support, to ensure optimal fixation.
The handpiece slides into the support, with or without a container (fig. 6).
The hole on the edge of the support is for recapping the needle. It enables to recap without risk of contamination.



To prevent accidental pricking, never leave an unprotected needle on the handpiece when on the support.

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Your SleeperOne functions

START UP / STOPPAGE WITH THE PEDAL

SleeperOne starts up as soon as you press one of the pedals. Each press is validated by one or two sound signals. If necessary, the «beeps» can be deactivated (see following page).
SleeperOne does not contain an on/off button, it automatically goes into low power consumption mode, as soon as the pedals are released. SleeperOne can be plugged into your mains installation to be turned off at night.

THE PEDAL FUNCTIONS

SleeperOne has different injection modes symbolised by the following pictograms on the pedals:

Picto-gram	Actions	Type of press	Sound signal validation (Number of "beeps")	Anaesthesias recommended	Complementary information
▶⏸	**Slow auto gradual speed with a 2 second pause every 4 seconds**	**a continuous press**	🔊	**Attached mucosa, palatal...** (infiltration into dense tissues)	Handpiece light continuously lit
▶	**Slow constant speed**	**a double press***	🔊 🔊	**Intraligamentary or intraseptal**	Handpiece light continuously lit. If there is no resistance to the injection, the speed will increase automatically by 50% after 35 seconds to reduce the injection time.
▶▶	**Fast gradual speed**	**a continuous press**	🔊	**Infiltration, nerve block/spix** (infiltration into easily extendable tissues, for sensitive patients)	Handpiece light continuously lit
▶▶	**Fast constant speed**	**a double press***	🔊 🔊	**Infiltration, nerve block/spix** (infiltration into easily extendable tissues)	Handpiece light continuously lit
⏮	**Plunger return**	**a short press** (less than 1 sec.)	🔊 🔊		The return stops automatically when the plunger has reached it's starting position.
◀	**Aspiration for a nerve block or infiltration**	**a continuous press**	🔊 - 🔊 - 🔊...	**Infiltration, nerve block/spix**	The aspiration is stopped by releasing the pedal. **The aspiration can only be performed after injecting a sufficient quantity of product (approx. 1/8 to 1/4 of a cartridge).**

*The double press is obtained in 2 ways:

- **You are starting the injection.** In this case, press once quickly, and then immediately press again on the same pedal. A double «beep» confirms your selection.
- **You already injecting.** Release the pedal for less than 2 seconds then press continuously on the same pedal. A double «beep» confirms your selection.

NOTE: After the 2 seconds, identified by a sound signal, the pedal is no longer in double press mode. A new continuous press will therefore trigger, the slow auto gradual speed or fast gradual speed, depending on the pedal.

⚠ **In case of patient sensitivity when using the fast speeds, use the constant slow or slow auto gradual speed.**

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Quantity of anaesthetic injected

The quantity injected is visible through the transparent container.
It is also indicated by a different number of «beeps» for each quarter of cartridge injected (see table below).

The «beeps» are only an indication, only the view of the cartridge through the container can determine the exact quantity injected.

Quantity injected	Number of "beeps"	Injection time in slow speed		Injection time in fast speed	
		Auto Gradual	Constant	Constant	Gradual
1/4 cartridge	1	2 mn 20 s	50 s	20 s	30 s
1/2 cartridge	2	4 mn 35 s	1 mn 30 s	35 s	45 s
3/4 cartridge	3	6 mn 50 s	2 mn 15 s	50 s	1 mn
1 cartridge (automatic plunger return)	4	9 mn 10 s	2 mn	1 mn 10 s	1 mn 20 s

Resistance during injection

The light on the handpiece flashes when there is resistance during injection:

Type of light	Level of resistance	Alarm sound signal	Information
Continuously lit	Low	-	Continue injecting
Slow flashing	Medium	-	Continue injecting
Fast flashing	High	-	Continue injecting
Off	Critical	(Long «Beep»)	Injection stops to prevent the cartridge from breaking. Plunger return before stoppage. The needle is blocked or the anaesthetic can not diffuse. Change needle or injection site.

Activate / Deactivate the pedals «beep» sounds

Press for approx. 3 seconds on the ⓘ button with a paper clip.
The deactivation is confirmed by a sound signal.

NOTE: This function does not deactivate the quantity «beeps».

To reactivate this function, press again for 3 seconds on the ⓘ button until you hear the beep.

Technical information? Our team is ready to help on +33 241 560 590 or sleeperone@dentalhitec.com

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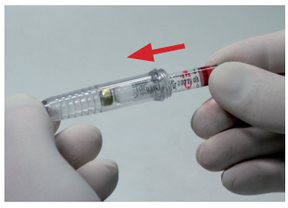
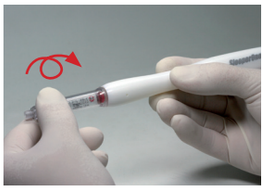
Installing / removing a cartridge and needle

TO INSTALL

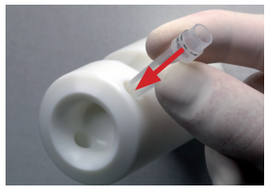


Make sure that the plunger is completely returned (press the ⏮ pedal).
Place a new cartridge in the container.
The use of a used cartridge can be the cause of injection malfunctions.



Screw the container onto the handpiece.

Screw the DHT needle onto the container.



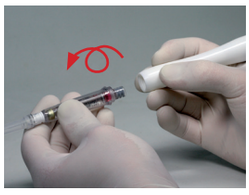
When you are ready to start working, remove the needle cap and place it in the dedicated hole on the handpiece holder.

Inject in fast speed ⏩ until the first drops come out of the needle. You are ready to begin.

TO REMOVE

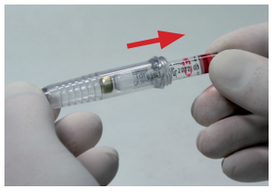
Press on the ⏮ pedal to return the plunger to it's initial position.

Recap the needle with the handpiece holder.



Unscrew the container.

Unscrew and incinerate the used needle with a device for medical waste.



Remove the cartridge and place it in a dispositive for medical waste. Clean and sterilise the container as indicated on the maintenance sheet.

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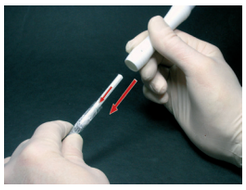
Cartridge breakage

Procedure to be respected imperatively to prevent serious damage to the equipment which is not covered by the manufacturer's warranty.

Keep the handpiece faced downwards at all times.
Replace the needle cap with the handpiece holder.

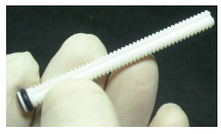
Unscrew the plastic container.



Inject in fast speed until the plunger is completely advanced and remove it from the handpiece.

Remove all of the glass debris, especially in the plunger's throat and inside the handpiece. Make sure that the plunger's black o'ring is not damaged. Confirm the absence of pieces of glass in the body of the handpiece.

You can run the plunger under water but dry it after with the low pressure air jet. **Never run the handpiece under water.**



To replace the plunger, press on the ⏮ pedal and present the plunger to the body, aligning the 2 throats with the 2 metallic rods inside the body.

Press lightly on the plunger until it is guided inside the body and returns to its initial position.

Never grease or oil your SleeperOne's plunger, it would cause future malfunctions.

Maintenance

The control box, the pedal

- Unplug the device before cleaning.
- Clean these parts with a clean cloth and an alcohol solution.
- Never use powerful solvents or aggressive chemical products.
- Never sterilise the control box or pedal.
- Never immerse the control unit or pedal in liquid.

The handpiece and handpiece holder

- Disinfect these 2 elements after each patient.
- Use disinfection products dedicated for this purpose.
- Never sterilise the handpiece.
- Never immerse the handpiece into a liquid.

Warning : try the product on a small surface beforehand to make sure that it will not deteriorate the surface of the handpiece or holder.

The plastic containers

Clean in a disinfectant bath after use, with or without Ultrasonics.

↓

Rinse thoroughly with water + dry

↓

Autoclave cycle at 134°C (275°F) according to ISO 17665*

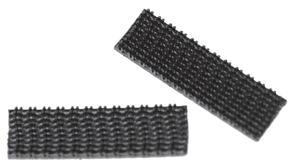
After disinfection, thoroughly rinse the container with demineralised water to remove all traces of disinfectant product. Failure to respect this rule can produce fast deteriorations (whitening, cracks...) which are not covered by the manufacturers warranty.

Spare parts

You can order extra accessories from your local dealer or by contacting Dental Hi TEC directly.

Plastic containers
(Ref. SA050 or SA051)

2.5m Low voltage power supply
(Ref. C2904)



Control box fixing adhesives
(Ref. SA0226)

Needles DHT

ø 0,30 (30G) - 16 mm
Ref. C3005

ø 0,30 (30G) - 9 mm
Ref. C3002

ø 0,40 (27G) - 13 mm
Ref. C3001

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Technical characteristics

Name: SleeperOne Model: S4
Device classification: IIA
Nominal voltage: CA 100-240 V 50/60 Hz
Ambient temperature: Tmra: 10-40°C
Altitude max.: 3000m
Class II power supply enclosed: 18V - 560 mA
Characteristics of the radio transmitter:
Frequency / Transmission power: 868.3MHz / max. 10mW EIRP
Data rate / Channel bandwidth / Modulation type : 120 kbps / 280 kHz / ASK

Do not use this device with a power supply other than the one supplied (FW7660).

Dimensions :
Handpiece: Diameter: 26 mm · Length: 228 mm · Weight: 70 g
Handpiece holder: Height: 75 mm · Width: 44 mm · Length: 44 mm
Control box : Length : 109 mm · Width : 78 mm · Height : 24 mm · Weight : 106 g
Wireless pedal: Length: 250 mm · Width: 180 mm · Height: 63 mm · Weight: 603g
Wire pedal (option) : Length: 180 mm · Width: 145 mm · Height: 33 mm · Weight: 320g
Cartridge to be used: 1.8 ml cartridge (ISO 11499)
Auto-off: After 10 minutes without use
Compliance: CE

We declare on our own liability that this product complies with the EC and CSA regulatory provisions.
In the interest of product improvement, Dental Hi Tec reserves the right to make modifications to its products without prior notice.

SleeperOne is intended for use in an electromagnetic environment where the electromagnetic interferences are controlled and defined in tables 1 & 2 on the following pages
The customer or user of the device must make sure that it is used in an environment as described and can help to prevent interferences by respecting minimal distance between RF communication devices (portable or mobile) (transmitters) and SleeperOne as recommended in table 3, depending on the transmission power of the communication device.

TABLE 1 - Electromagnetic emissions

Emission tests	Compliance:	Electromagnetic environment – Directives
RF emissions CISPR 11	Group 1	SleeperOne uses RF energy only for its internal function. Furthermore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The use of SleeperOne is suitable for use in all types of establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonics transmission	Class A	
IEC 61000-3-3 Voltage fluctuations / Flicker emissions	Complies	

TABLE 2 - Electromagnetic immunity

Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	
Voltage dips, short interruptions and voltage variations on power supply input lines	< 5% UT (> 95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	0 V / 10 ms 92 V / 100 ms 161 V / 500 ms 0 V / 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended to use an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c mains voltage prior to application of the test level.

Immunity test	IEC 60601 Test level required	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the device should be observed to verify the normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b) Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Electromagnetic environment – guidance

Portable or mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

d = [3,5/V1] √P

d = [3.5/E1] √P 80 MHz to 800 MHz

d = [7/E1] √P 800 MHz to 2,5 GHz

Where P is the maximum output power rating of the transmitter in watts (W), according to the manufacturer and d is the recommended separation distance in metres (m)[b].

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: ((·))

TABLE 3 - Recommended separation distances between portable & mobile RF communications equipment and SleeperOne

	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 kHz toà 800 MHz	800 kHz to 2,5 GHz
Rated maximum output power of transmitter (W)	$d=[3,5]\sqrt{P}$	$d=[3,5]\sqrt{P}$	$d=[7]\sqrt{P}$
0.01	0,12	0,12	0,12
0.1	0,37	0,37	0,37
1	1,17	1,17	1,17
10	3,69	3,69	3,69
100	11,67	11,67	11,67

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

This appliance must not be disposed of with household waste

It contains dangerous substances, which can have important consequences for the environment and human health. It must be recycled in a specific treatment facility.

If you are concerned by the European WEEE directive, please contact your distributor or the Dental Hi Tec company who will take all of the necessary measures towards the collection and recycling of the device.

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Warranty conditions

DENTAL Hi Tec offers a two-year warranty for SleeperOne from the date of purchase.
This warranty does not apply to the sterilisable accessories. The implementation of the warranty requires the submission of the original proof of purchase indicating the date of purchase. This warranty only applies if the SleeperOne is used in compliance with the operating instructions and tolerances as indicated in this manual.

The warranty is invalid if:

- a technical repair is made to the device by an unapproved person.
- the device is damaged by an external source (lightning, fire, water damage, negligence or accident), by improper use or non-compliant installation.
- the device is adapted to operating norms that are different from those indicated on the material safety data sheet located under the control unit.
- the purchase documents are changed or altered.
- the serial number of the device has been made unreadable.

In no case shall the application of this warranty constitute an entitlement to complete replacement of the device or give the right to claim damages. SleeperOne cannot be subject to return outside of the warranty clauses.

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SleeperOne®

For any complementary information,

contact our advisors:

Clinical & technical information: **+33 241 560 590**

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DENTAL HI TEC

Innovation for dental anaesthesia

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